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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/036,819	03/09/1998	A. SAID EL SHAMI	107-145D-C	6406

7590

11/14/2003

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EXAMINER
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DEVI, SARVAMANGALA J N

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 11/14/2003

36

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
09/036,819

Applicant(s)  
El Shami

Examiner  
S. Devi, Ph.D.

Art Unit  
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE two MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Sep 8, 2003
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☒ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 56 is/~~are~~ pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/~~are~~ withdrawn from consideration.
- 5) ☒ Claim(s) 56 is/~~are~~ allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 33
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: Attachment

**ATTACHMENT TO *Ex parte QUAYLE* ACTION**

- 1) This application is in condition for allowance except for the following formal matters:  
The contents of Tables 1-19 are illegible and these Tables require replacement.  
Prosecution on the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

A shortened statutory period for reply to this action is set to expire **TWO MONTHS** from the mailing date of this letter.

**Supplemental Appeal Brief**

- 2) Acknowledgment is made of Appellant's Supplemental Appeal Brief filed 09/08/03 (paper no. 35), which has been entered.

**Supplemental Amendment**

- 3) Acknowledgment is made of Appellant's amendment filed 09/08/03 (paper no. 34) which has been entered.

**Status of Claims**

- 4) Claim 56 has been amended via the amendment filed 09/08/03.  
Claim 55 is pending and is under examination.

**Rejection(s) Withdrawn**

- 5) The rejection of claim 56 under 35 U.S.C § 112, second paragraph, as being indefinite and under 35 U.S.C § 103(a) as being unpatentable over the count of Interference # 103,933, is withdrawn in light of Appellant's amendment to the claim and arguments.

The arguments advanced in the supplemental Appeal Brief, filed 09/08/03, are found to be persuasive. Appellant's submission that neither the count of Interference # 103,933 involved in application 06/784,857, nor the Board-decided claims 1-27 of the earlier filed application, 07/303,71, included the instantly claimed method, is persuasive. Appellant's submission that the instant claim 56, which utilizes the combination of four specific elements: testosterone analyte; radioiodinated-6-hydroxy testosterone 19 carboxymethyl ether histamine labeled analog; testosterone-specific antibody; and sulfobromophthalein blocking agent, is non-obvious over the overly broad claims involved in the Interference, is persuasive. This in combination with the unexpected result pointed to by the Appellant on page 25 of the specification, i.e., the inhibition

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of binding of the recited labeled analog by the blocking agent, sulfobromophthalein, without displacing testosterone bound to albumin, renders the instant claim 56 non-obvious over the Interference count.

#### Remarks

- 6) In light of the arguments advanced in the supplemental Appeal Brief, claim 56 is allowable.
- 7) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Fax Center located in Crystal Mall 1. The transmission of such papers by facsimile must conform with the notice published in the Official Gazette, 1096 OG 30, November 15, 1989. The CM1 facsimile center receives transmissions 24 hours a day and 7 days a week. The RightFax number for submission of before-final amendments is (703) 872-9306. The RightFax number for submission of after-final amendments is (703) 872-9307.
- 8) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (703) 308-9347. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

November, 2003

  
S. DEVI, PH.D.  
PRIMARY EXAMINER